Department of Toxic Substances Control

Guidelines for Internal Coordination and Implementation of Consumer Product Activities

Developed by the Toxics in Consumer Products Team, Submitted March 2008

Welcome

DTSC launched the Toxics in Consumer Products team in October 2007 to develop guidelines for efficient coordination and communications, timely product testing, document collection, database storage and organized enforcement protocol that the Department can use for many consumer goods facing new regulations governing their content.

The team came together with members from many areas of the Department, including legal, enforcement and the Environmental Chemistry Laboratories. Work began shortly after California's new Lead-Containing Jewelry Law took effect and as DTSC investigators for the first time in history began checking the lead content of children's jewelry.

At the time, California was the first state in the nation to have a law regulating lead in jewelry. Legislators and Gov. Arnold Schwarzenegger had enacted the law because if lead enters the bloodstream of a young child in sufficient quantity, it is known to affect the child's intellectual development. In high enough quantities, lead can even kill.

While children's jewelry was the initial target of the new law, the law also contained provisions extending lead content standards to adult jewelry and jewelry used in body piercings as of March 1, 2008.

In addition, DTSC had begun enforcement of the state's Toxics in Packaging Law, and it was anticipated that more legislation on consumer goods was likely to develop.

The team hopes the guidelines herein provide a helpful overview of the tasks, issues and scope of work involved when DTSC is called upon to regulate toxics in consumer products.

Peter Wood and Mike Berriesford, team leaders

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Team Charter
Toxics in Consumer Products

Mission

The Toxics in Consumer Products team envisions safe, proper and consistent management of the consumer products regulated by DTSC and effective coordination with sister agencies (e.g. federal Consumer Products Safety Commission, California Department of Public Health, California Department of Pesticide Regulation, California Integrated Waste Management Board and the California Air Resources Board) to ensure compliance with the statutes and regulations governing toxic substances in consumer products.

Duration

This team is expected to remain in place until July 1, 2009. However, the stated timeframe may be extended if necessary.

Goal

The goal of the Toxics in Consumer Products Team is to establish an all-encompassing strategy for the implementation and enforcement of all regulated consumer products and other requirements within DTSC's purview and to ensure effective internal and external communication and coordination with affected programs and stakeholders as new products become subject to regulation.

As of early 2008, DTSC had regulatory authority over the following consumer products:

- Toxics in Packaging (TIP)
- Lead in Jewelry (LIJ)
- Restriction of Hazardous Substances (RoHS) in Covered Electronic Devices
- Mercury-Added Products (i.e. thermostats, relays, switches and measuring devices)
- Prohibited Chemical Toilet Additives

- Lighting Efficiency and Toxics Reduction Act (AB1109)

Phase 1 (FY 07/08)

The initial work of the team will be completed by borrowing resources and delaying other enforcement work. During Phase 1, resources consisting of staff from program areas including Pollution Prevention Program, Environmental Chemistry Laboratory, Human and Ecological Risk Division, Enforcement and Emergency Response Program, and Hazardous Waste Management Program will be assigned to develop strategies to address all consumer product bans. This includes: (1) methods to identify industries, supply chains, manufacturers, and distributors; (2) inspection and field sampling techniques; (3) industry outreach mechanisms; (4) a media plan with a risk communication element that will provide timely and meaningful information to the public regarding the program's findings; (5) define the elements of compliance assistance; and, (6) develop standard analytical methods and procedures. Current year staffing resources are also scheduled to develop enforcement strategies consistent with statutory authorities, to pursue enforcement actions against targeted industries, and to propose recommendations for regulation development needed to guide future implementation of the Toxics in Consumer Products enforcement program. Targeted efforts in FY 07/08 will start with Lead in Children's Jewelry, a restriction that came into effect on September 1, 2007.

Phase 2 (FY 08/09)

The team intends to implement Phase 2 by dedicating additional staff to implement the Toxics In Consumer Products enforcement project and (1) enforce Health and Safety Code, Division 20, Chapter 6.5, Toxics in Consumer Products; (2) continue enforcement strategies and priorities in consultation with DTSC's Pollution Prevention Program, Hazardous Waste Management Program, and the Environmental Chemistry Laboratory; (3) coordinate and optimize the authority of sister agencies (e.g. federal Consumer Products Safety Commission, California Department of Public Health, California Department of Pesticide Regulation, California Integrated Waste Management Board and the California Air Resources Board) to enforce statutes and regulations associated with regulated substances in consumer products; and, (4) encourage manufacturers and retailers to move toward Green Chemistry in the production and sale of consumer products and packaging. As the Toxics in Consumer Products team matures, DTSC will assess the progress made to date, the accomplishments achieved, the future resources needed to sustain the current program, and the effectiveness of the level of effort invested during FY 07/08 and FY 08/09.

Background

The Toxics in Packaging Prevention Act, Lead-Containing Jewelry statutes, Restriction of Hazardous Wastes in Covered Electronic Devices provisions of The Electronic Waste Recycling Act and Mercury-Added Products statutes are precedent-setting pollution prevention measures that address problems at the source rather than the typical approach of regulating a material when it becomes a waste. The prohibitions in the first three laws became effective January 1, 2006, September 1, 2007, and January 1, 2007, respectively. The elimination of the sales of certain mercury-added products occurs in three phases; January 1, 2006, July 1, 2006 and January 1, 2008. However, the Prohibited Chemical Toilet Additives law predates all of the aforementioned consumer product regulatory schemes and banned the sale and use non-biodegradable toxic chemicals in chemical toilets beginning January 1, 1979, and was later expanded to include halocarbons on July 1, 1988. The most recent consumer product statutory regime regulated by DTSC, the Lighting Efficiency and Toxics Reduction Act, creates a phased-in ban on the manufacture and sale of certain lighting products beginning on January 1, 2010, and expands with subsequent bans in 2012 and 2014.

Toxics in Packaging Prevention Act

The Toxics in Packaging Prevention Act (TPPA) was created by Assembly Bill (AB) 455 (Chu, Chapter 679, Statutes of 2003 and was amended the following year) targets four heavy metals; lead, mercury, cadmium and hexavalent chromium, all of which present serious health risks at relatively low concentrations. TPPA prohibits, with some exceptions, the sale of any package or packaging component, or any product in a package, that includes: (i) any amount of intentionally introduced lead, mercury, cadmium, or hexavalent chromium (referred to as "regulated metals"); or (ii) more than 100 parts per million of these metals incidentally present in the package or packaging component. Exemptions are allowed, but must be approved by DTSC.

Manufacturers and suppliers are required to furnish a certificate of compliance to the purchaser of a package or packaging component. A copy of the certificate must be retained by the manufacturer or supplier and by the purchaser of the package, and the manufacturer or supplier must provide a copy to DTSC, upon request. Manufacturers and suppliers are subject to criminal, civil or administrative penalties for violation of the requirements specified above.

Lead-Containing Jewelry

The Lead-Containing Jewelry statutes were established by AB 1681 (Pavley, Chapter 415, Statutes of 2006) and set allowable limits of lead in jewelry and substantially reduce or eliminate exposure to lead and the harmful health effects that it can cause, especially to children in their formative years.

In June 2004, the Attorney General filed a lawsuit against several California-based retailers alleging they violated Proposition 65 by failing to warn consumers about the health risks of exposure to the lead contained in certain jewelry they were offering for sale. Testing by the state demonstrated high levels of lead in both the metallic and nonmetallic components of the jewelry targeted in the case. The amounts were well above the level that triggers the requirement to provide a Proposition 65 warning to consumers. A settlement of the Proposition 65 lawsuit in the form of a consent judgment was reached in January 2006. Entities that have entered into the consent judgment or that do so in the future are not subject to DTSC's enforcement action for violations of the Lead in Jewelry Act, but such cases are transferred to the Attorney General for further handling pursuant to the consent judgment. All other entities are subject to civil penalties only.

RoHS in Covered Electronic Devices

The Electronic Waste Recycling Act was established by Senate Bill (SB) 20 (Sher, Chapter 526, Statutes of 2003) and related amendments found in SB 50 (Sher, Chapter 863, Statutes of 2004). The Act makes it unlawful to sell, on or after July 1, 2004, a covered electronic device in California to a consumer unless the California Integrated Waste Management Board or DTSC determines that the manufacturer of that device is in compliance with the Act. Resources were received to implement RoHS in Covered Electronic Devices in FY 2005-06.

Mercury-Added Products

The Mercury-Added Thermostats, Relays, Switches, and Measuring Devices statutes were established by AB 1415 (Pavley, Chapter 578, Statutes of 2005) and set a series of dates beyond which the sale of a number of devices containing mercury are banned. Beginning January 1, 2006, this law makes it illegal to sell, or distribute for promotional purposes, a mercury-added thermostat, unless the mercury-added thermostat meets specified criteria. This law also bans the sale, or distribution for promotional purposes, on or after July 1, 2006, of certain new or refurbished mercury-added products, a mercury switch or mercury relay,

unless the use of the product is required under a federal law or federal contract specification or if the only mercury-added component in the product is a button cell battery. Finally, this law bans the sale or distribution for promotional purposes, of a mercury diostat, as defined, or a new or refurbished oven or gas range containing a mercury diostat, on or after January 1, 2008.

Prohibited Chemical Toilet Additives

The Prohibited Chemical law (Chapter 1039, Statutes of 1977) has the distinction of being the first consumer product statutory scheme implemented by DTSC. Initially, this law banned the sale or use of a non-biodegradable toxic chemical in a chemical toilet, recreational vehicle, or waste facility of a vessel on or after January 1, 1979. This law was later amended (Chapter 874, Statues of 1987) to increase its scope to include the use or sale of halocarbon chemicals on or after July 1, 1988.

Lighting Efficiency and Toxics Reduction Act

The California Lighting Efficiency and Toxics Reduction Act was created by AB 1109 (Huffman, Chapter 534, Statues of 2007). AB 1109 enacts a cradle to cradle concept that links to DTSC's Green Chemistry Initiative by restricting the manufacture and sale of lighting products and makes recommendations on methods for collecting and recycling end-of-life light bulbs. Specifically, AB 1109 creates a phased-in ban on the manufacture and sale of certain lighting products that mirrors the European Union's restrictions of hazardous substances in general purpose lighting products. The phase-out of affected products begins on January 1, 2010, and expands with subsequent bans in 2012 and 2014.

Team Sponsor Commitments

- Allocate time to meet with the team for progress updates.
- Advise the team as to executive vision and values as they relate to the team mission.
- Invite team leader to DTSC's executive staff meeting once per month to brief management on the progress of the team.
- Review and approve project changes or recommendations.
- Identify team resources as necessary.

- Assist with removing barriers to team success; including providing guidance as necessary to keep the project timely and within scope.
- Provide direction and resources, including materials, training and expertise to process improvement teams ensuring a successful process improvement team outcome.

Stakeholders

- Packaging manufacturers/suppliers/end users
- Jewelry manufacturers/suppliers/retailers
- Toxics in Packaging Clearinghouse (TPCH)
- Interstate Mercury Education and Reduction Clearinghouse (IMERC)
- California Retailers Association
- California Grocers Association
- Wal-Mart
- Electronics manufacturers/suppliers/retailers
- Federal Consumer Products Safety Commission
- California Department of Justice, Office of the Attorney General
- California Department of Public Health
- California Department of Pesticide Regulation
- California Air Resources Board
- California Integrated Waste Management Board
- Other product specific entities to be identified

Team Authority

- Pursue information and recommend approaches necessary to achieve the needs of the mission and the goals stated above.

- Allocate time within the team member's work day to attend team meetings.
- Obtain authorization from the team sponsor to disseminate final team deliverables.
- The recommendations formulated and presented by the team will reflect team decisions made through a consensus process.

Project Approach

The team is designed to meet the Governor's Action Plan Initiative 6 by (1) protecting California's environment through strong enforcement of existing laws, and (2) supporting the Cal/EPA's Strategic Goal 4, which holds that communities are to be free from unacceptable human health and ecological risks due to exposure from hazardous substances and other potential harmful agents.

The team also supports DTSC's Strategic Plan Goal 2: Minimize and/or eliminate adverse environmental and public health effects resulting from the past, present and future generation and management of hazardous waste. Specifically, this team addresses:

- Objective 1: Monitor California's hazardous waste storage, recycling, treatment and landfill capacity to manage all hazardous waste in a safe and efficient manner; and
- Objective 4: Reduce hazardous waste generation.

Schedule

The team will initially meet once each week for approximately one-two hours during the formative stage of the project. As the project progresses, the team may elect to meet less frequently, but no less than once per month. The team may meet more frequently to address specific issues as necessary. The team will continue to operate until disbanded by the team sponsor.

Monthly Project Reports

The team leader will provide to the team sponsor, other team leaders and the team itself, a brief report of activities during the previous month describing the progress the team has made toward accomplishing the team's deliverables.

Team Member Commitments

- Team members will make attendance at team meetings a priority and will provide agenda items for team meetings.
- Completion of team tasks is an essential and integral part of team participation.
- The team leader will prepare meeting agendas and team meeting minutes.
- In addition to project discussions held during the time set aside for regularly scheduled team meetings, team members are at all times, encouraged to discuss the project and communicate ideas with each other to foster project momentum.
- Team members will contribute by sharing knowledge and technical expertise.
- Team members will select an alternate team leader to represent the team when the team leader is not available to perform this function.

Team management guidelines are included in “Key Elements of the Team Approach” (attached)

Key Elements of the Team Approach

(A brief primer, Nov. 2006)

Teams are structured around specific process improvement pilot projects like Permit Renewals and Voluntary Cleanups. Teams last until the project is completed.

Teams will adopt a team charter at their first meeting using a draft charter developed for these pilot projects.

Each office which provides staffing to a project must be represented on each team.

All team members are kept responsible for laying out the schedule for each project. A model Gantt chart, which documents a preferred work flow, will serve as the basis for these decisions.

Each team member is responsible to the rest of the team for completing their portion of the project in accordance with the agreed-upon schedule.

All members of the team are responsible for the completion of the project.

The teams will have the support of the Performance and Environmental Indicators Team for help with team organization, decision making tools and general counsel to enable the teams to become established and successful in their mission.

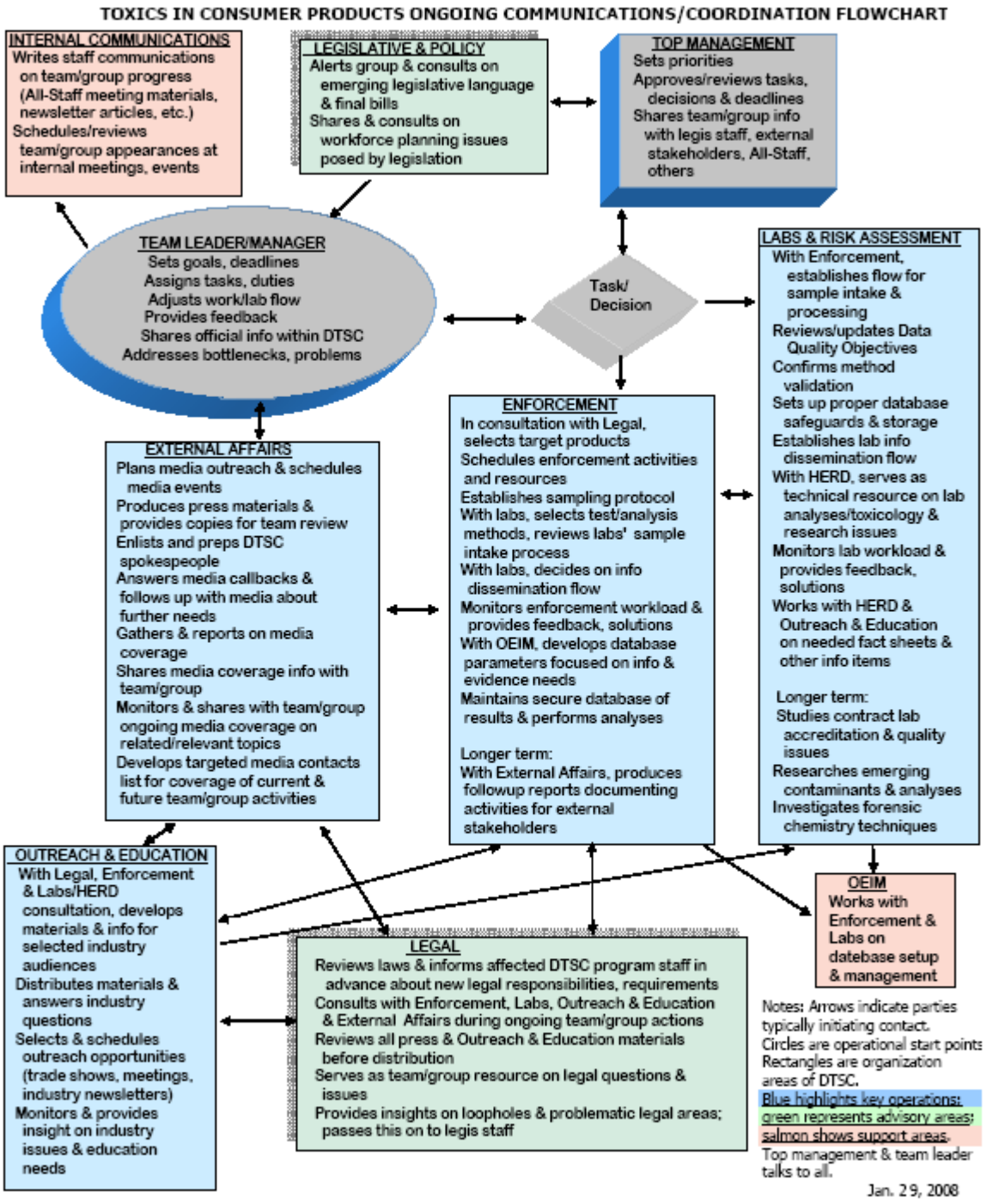
The Team Leader serves as the hub for communication, planning, coordination, tracking and reporting for each project.

The team will use some form of shared decision-making. The Team Leader cannot dictate to any other team member what their actual view or input must be.

Team members will be responsible for producing their assigned work products. This will include members in line staff roles as well as team members representing traditional support offices such as Public Participation or CEQA.

Team Leaders should complete a class in Team Leadership as soon as possible after being selected.

Team members should complete a class in Team Building and Participation as soon as possible.


TOXICS IN CONSUMER PRODUCTS ONGOING COMMUNICATIONS/COORDINATION FLOWCHART
INTERNAL COMMUNICATIONS
Writes staff communications on team/group progress (All-Staff meeting materials, newsletter articles, etc.)
Schedules/reviews team/group appearances at internal meetings, events
LEGISLATIVE & POLICY
Alerts group & consults on emerging legislative language & final bills
Shares & consults on workforce planning issues posed by legislation
TOP MANAGEMENT
Sets priorities
Approves/reviews tasks, decisions & deadlines
Shares team/group info with legis staff, external stakeholders, All-Staff, others
TEAM LEADER/MANAGER
Sets goals, deadlines
Assigns tasks, duties
Adjusts work/lab flow
Provides feedback
Shares official info within DTSC
Addresses bottlenecks, problems
Task/ Decision
LABS & RISK ASSESSMENT
With Enforcement, establishes flow for sample intake & processing
Reviews/updates Data Quality Objectives
Confirms method validation
Sets up proper database safeguards & storage
Establishes lab info dissemination flow
With HERD, serves as technical resource on lab analyses/toxicology & research issues
Monitors lab workload & provides feedback, solutions
Works with HERD & Outreach & Education on needed fact sheets & other info items
Longer term:
Studies contract lab accreditation & quality issues
Researches emerging contaminants & analyses
Investigates forensic chemistry techniques
EXTERNAL AFFAIRS
Plans media outreach & schedules media events
Produces press materials & provides copies for team review
Enlists and preps DTSC spokespeople
Answers media callbacks & follows up with media about further needs
Gathers & reports on media coverage
Shares media coverage info with team/group
Monitors & shares with team/group ongoing media coverage on related/relevant topics
Develops targeted media contacts list for coverage of current & future team/group activities
ENFORCEMENT
In consultation with Legal, selects target products
Schedules enforcement activities and resources
Establishes sampling protocol
With labs, selects test/analysis methods, reviews labs' sample intake process
With labs, decides on info dissemination flow
Monitors enforcement workload & provides feedback, solutions
With OEIM, develops database parameters focused on info & evidence needs
Maintains secure database of results & performs analyses
Longer term:
With External Affairs, produces followup reports documenting activities for external stakeholders
OUTREACH & EDUCATION
With Legal, Enforcement & Labs/HERD consultation, develops materials & info for selected industry audiences
Distributes materials & answers industry questions
Selects & schedules outreach opportunities (trade shows, meetings, industry newsletters)
Monitors & provides insight on industry issues & education needs
LEGAL
Reviews laws & informs affected DTSC program staff in advance about new legal responsibilities, requirements
Consults with Enforcement, Labs, Outreach & Education & External Affairs during ongoing team/group actions
Reviews all press & Outreach & Education materials before distribution
Serves as team/group resource on legal questions & issues
Provides insights on loopholes & problematic legal areas; passes this on to legis staff
OEIM
Works with Enforcement & Labs on datebase setup & management
Notes: Arrows indicate parties typically initiating contact.
Circles are operational start points
Rectangles are organization areas of DTSC.
Blue highlights key operations; green represents advisory areas; salmon shows support areas.
Top management & team leader talks to all.
Jan. 29, 2008

Legal Strategy Template
Toxics in Consumer Products

Ensuring that legal resources and consultation are available during legislative and regulatory analysis, enforcement planning and activities and followup

Goal

The primary goal of a legal strategy is to ensure that legal resources are available on a timely, updated basis to inform management and supply consultation on toxics in consumer products efforts. This is necessary through the complete process, from enforcement planning through to company notification and, potentially, court cases. Currently, the legal work is focused on two recent consumer products initiatives: The Toxics in Packaging Prevention Act and the Lead in Jewelry statutes.

Basic Concepts – Toxics in Packaging

The Toxics in Packaging Prevention Act is intended to keep four "regulated metals" out of packaging so that metal-laden packaging is kept of the state's solid waste landfills. The Legislature made findings that "packaging comprises a significant percentage of the overall solid waste stream" and further found that lead, mercury, cadmium and hexavalent chromium are of particular concern within the solid waste stream. Thus, these are the four metals that are subject to the requirements and prohibitions under this statutory scheme.

It should be noted that the Toxics in Packaging Prevention Act is based very closely on model legislation initially proposed by the Coalition of Northeastern Governors. This model legislation has been enacted by at least 19 states. Accordingly, guidance and clarification of various provisions is available from these states and the Toxics in Packaging Clearinghouse, of which 10 of these states are members.

The Toxics in Packaging Prevention Act is codified at Article 10.4 of Chapter 6.5 of Division 20 of the California Health and Safety Code, commencing with Section 25214.11. It may be cited as the Toxics in Packaging Prevention Act. It was added by AB 455 (Ch. 679, Chu) in 2003 and was substantially amended by AB 2021 (Ch. 445, Chu) in 2004. There was a more modest amendment made by SB 774 (Ch. 659, Ridley-Thomas) in 2007.

Basic Concepts – Lead in Jewelry

The Lead in Jewelry statutory provisions are intended to keep excess amounts of lead out of both children's and adult jewelry. The lead in jewelry statutory provisions are based very closely on a Consent Judgment entered into by the California Department of Justice (Attorney General's Office) and numerous corporate defendants in settlement of a Proposition 65 failure to warn case -- related to lead in jewelry -- that was brought by the Attorney General's Office.

The lead-containing jewelry statutes are codified at Article 10.1.1 of Chapter 6.5 of Division 20 of the California Health and Safety Code, commencing with Section 25214.1. The statutes were enacted by AB 1681 (Ch. 415, Pavley) in 2006. There have been no amendments to this area of law.

Internal Communications and Coordination

The principal area of concern that requires internal communication and coordination regarding legal issues arises with the passage of a new statutory scheme or requirement regarding this topic. Basically, DTSC needs a consistent means of informing affected program staff and support program staff when there is a new program or area of responsibility conferred upon DTSC. Affected staff members need to know what the mandate is, when it goes into effect and any problems or limitations that may be in play. Staff also need to know if positions have been allocated and, if not, whether DTSC will be pursuing a Budget Change Proposal to seek more positions.

Assigned staff need to develop both internal and external communications strategies to get the word out to staff, the regulated community and the public on what the new program requirements are. These strategies must be multi-faceted and overlapping. Early upfront work and communications are vital.

Emerging Legal Issues

It is extremely likely that DTSC will be given additional areas of responsibility in the field of toxics in products. Such responsibilities are virtually always the result of newly enacted legislation. In order for DTSC to efficiently and effectively implement any new program responsibilities, affected staff must be aware of any such responsibilities as soon as is feasible. This means that the Department's Legislative Affairs Office needs

to bring pertinent staff members into the analytical process as a bill is under discussion and review by the Legislature. This would ensure that programmatic concerns are addressed at the earliest possible date.

To this end, the Legislative Affairs Office should assign a lead analyst to function as a team leader to ensure that effective coordination (see Communication Flowchart) and meaningful analysis will take place by all affected programs within DTSC and that pitfalls are avoided. Programmatic concerns can be addressed through proposed amendments to avoid implementation problems after a bill has been enacted into law. Such coordination should also ensure the development of Budget Change Proposals and related vehicles to provide for adequate resources and effective implementation of new legislation. Once the new legislation is enacted, responsibility for implementation will be transferred to an implementation team led by program staff. The legislative team leader may temporarily remain on this team to ensure a smooth transition.

Outreach and Education Strategy Template
Toxics in Consumer Products

Planning for comprehensive information-sharing for industry and the public

Goal

The purpose of an outreach and education strategy is to ensure the regulated community is aware of new requirements and understands how to comply with them. Effective and wide-reaching outreach and education should ideally produce enhanced compliance. Additionally, the public should be made aware of new consumer product laws and regulations through multiple information sources so consumers can make informed purchase decisions.

Identify Audiences

Program staff must identify and properly notify industry goups that are or will be subject to a new law and/or regulation. Product bans and restrictions typically impact the entire distribution chain from manufacturers through importers, distributors, transporters, wholesalers and retailers. Therefore, the audience is very large, and will likely include notifying entities that are based outside California as well. Various sources can be consulted to identify affected entities and coordinate outreach and education activities, including:

A. Relevant trade associations (e.g., California Retailers Association, California Grocers Association)

B. Targeted Internet searches (e.g., SIC Code searches)

C. Fee-based database searches (e.g., Harris Info)

D. Board of Equalization (BOE), Tax Policy Division sends regular notices to sales and use tax filers in California. BOE has allowed DTSC to insert a “flyer” containing information about new requirements in their mailings but it must be coordinated well in advance (contact: Marty Miranda at BOE).

OPTIONS:

- Distribute flyer with BOE mailings -- monthly, quarterly and annually based on amount of sales and use tax filed by business. Mass mailing printing is coordinated with the Office of State Printing. BOE has specific paper and size requirements for inserts.

- Submit article in BOE's quarterly Tax Information Bulletin (targets approximately 500,000 sales and use tax filers)

E. Other state and local agencies (e.g., Department of Public Health Childhood Lead Poisoning Prevention Branch, CIWMB, County HHW programs)

F. Federal agencies (e.g., Consumer Product Safety Commission, U.S. EPA)

G. Other agencies (e.g., European Union for RoHS)

H. Organizations (e.g., Toxics in Packaging Clearinghouse, Center for Environmental Health, Sierra Club)

I. Elected officials

J. Media, including trade journals and magazines

Develop and Distribute Information

Materials are developed by assigned program staff and routed through management, Office of External Affairs (OEA) and Office of Legal Counsel (OLC) for approval/review. Materials can be posted on the web site, mailed and/or emailed with followup phone calls and meetings, as appropriate, to ensure that materials are received and to inquire about specific questions and requests. Materials may include:

A. Web site content

B. Fact sheet(s)

C. Notification letters/mailings

D. Brochures

E. Training/speaking engagements/meetings

- Conference attendance
- Handouts at booths
- Presentations
- Gather contacts list from show/meeting attendees

F. Newsletters

G. Frequently asked questions

H. Press release(s) and supporting materials (created by OEA, reviewed by program staff)

- Key media messages
- Translations of fact sheets, FAQs, press releases and supporting material, key media messages and other public documents (Contact Heidi Nelson or Jeanne Garcia with OEA)
- Webcasts or other online training

Internal Coordination

Program staff must consult within DTSC to coordinate effective education and outreach activities and ensure successful implementation of the law and regulations.

A. With OEA, outreach information must be finalized and timing set for release:

- Submit outreach materials for series of reviews
- Submit web site material for approval/posting (submit through program's web posting contact)

B. Coordinate with OEA on the following:

- Press release content and production
- News conferences, media events, media availabilities, media interviews and other media activity

C. Inform regulatory assistance officers (RAOs) about program contacts and invite them to training on the law/regulations

D. Environmental Chemistry Laboratory (ECL)

- Invite lab staff to attend training on the law/regulations
- Review relevant testing SOPs

E. ECL can assist with media activities as needed

F. Enforcement and Emergency Response Program (EERP)

- Provide inspectors with training on the law/regulations
- Discuss key enforcement issues and priorities (agree on scope of what is covered by law/regulation)
- Help coordinate enforcement target selection as needed
- Inform EERP that complaint hotline information will be provided to the public to report any suspected violations of the law/regulations
- EERP can assist with media activities as needed

G. Office of Legal Counsel (OLC)

- Establish legal contact person
- Request assistance with legal issues/interpretations
- Submit outreach materials for review
- OLC can assist with media activities as needed

H. Office of Environmental Information Management (OEIM)

- Set up general mailbox for inquiries (send general Work Order request)
- Set up listserv (contact Michele Garcia)
- OEIM can assist with media activities as needed (i.e., post news releases and supporting charts, pictures and other materials)

I. Human and Ecological Risk Division (HERD)

- Consult with HERD to develop risk scenarios of most concern
- Coordinate public message(s)

I. Pollution Prevention (P2)

- Contact P2 regarding partnering with the Green Chemistry Initiative to identify low-toxicity alternatives to the banned materials and develop recommendations for materials that have a low environmental impact during the product lifespan
- Work with P2 to inform affected industries of the possible and preferred alternatives to banned materials

J. DTSC Management

- Submit initial strategy with detailed information, activities and timeframes
- Provide updates on progress via daily/weekly reports on activities, issues briefings, etc.
- Participate in media interviews and other media activities as needed

Compliance Assistance

A large component of education is compliance assistance, which includes answering questions from the regulated community, interested stakeholders and the public. Recurring questions should be compiled as frequently asked questions and posted on the web site. Outstanding issues may need to be addressed though legislative changes and/or regulation package.

Enforcement Strategy Template Toxics in Consumer Products

Setting the stage for proper sampling, documentation, sampling methodologies, data management, notification and followup

Goal

The primary goal of a product enforcement strategy is to identify the source of a non-compliant product and remove the product from commerce as quickly as possible. The identification of the product manufacturer, distributor, supplier and/or importer – through the distribution chain -- will allow for the fastest and most efficient removal of the non-compliant product from the marketplace.

Identify Selection Methodology and Sampling Plan

It is important to develop and employ a standardized approach to identify those potentially non-compliant products with the greatest potential to adversely impact public safety and the environment. The methodology selected should be tailored to the regulated product and include screening criteria along with confirmation testing that includes data quality objectives (DQO). Establishing DQOs will help determine when enough data of sufficient quality has been collected to enable accurate decision making. (sample attached)

Internal Coordination

Various programs within DTSC must be engaged to ensure a successful enforcement initiative.

A. Office of External Affairs (OEA)

- Outreach to industry must be in progress well before enforcement activities begin
- How? Mailings/Fact sheets/Web postings/Newsletter articles/Conferences, etc.
- To whom? Regulated community/Public
- Duty officers in the loop?

B. Environmental Chemistry Laboratory (ECL)

- Ensure adequate lab resources and testing methodologies
- Plug lab into the planning

C. Enforcement and Emergency Response Program (EERP)

- Provide inspectors with training of the law/regulations
- Coordinate enforcement target selection
- Inform EERP that complaint hotline information will be provided to report any suspected violations of the law/regulations

D. Office of Legal Affairs

- Establish an OLA contact person
- Discuss legal issues/interpretations (e.g. handling, disposal options, weak language)
- Confirm targeted entity/product covered by statute

E. Office of Environmental Information Management (OEIM)

- Consult and establish data tracking needs and setup

F. DTSC Management

- Review and get buy-in for enforcement plans

G. Human and Ecological Risk Division (HERD)

- Identify public health risk scenarios of most concern
- Coordinate public message

H. Pollution Prevention (P2)

- Identify alternative materials

Sampling Report

It is important that the sampling event be properly documented in the form of a narrative report and that a uniform procedure is followed to ensure

statewide consistency. The recommended format of the Sampling Report is as follows:

A. Date and time of violation observed (date and time of sampling)

B. Location where sampling occurred: Physical address

C. A description of the covered product giving rise to the violation

- Sample I.D. number with photograph of the product sampled
- ICP lab data characterizing the product that matches sample ID (repeat in D.)
- Type of product matrix
- Any identification markings, UPC or bar code and copy of receipt

D. All other test data and supporting documents

Laboratory Analysis

In the absence of a prescribed test method in either the implementing statute or following regulations, careful consideration should be given to selecting the test method used for total metals analysis of the product. The selection of the desired test method should be identified in the "Target Selection Strategy" and take into consideration the following factors:

- Selecting test method 3050B will measure the product for both compliance with the law and determine whether a non-compliant product meets the hazardous waste criteria.
- Selecting test method 3051/52 may be superior in extracting total metals in a plastic matrix; however, the results obtained by this method cannot be used for waste classification purposes.

Data Management

The importance of an accurate and comprehensive data management system cannot be overstated. Careful consideration must be given to both the collection and tracking of the data generated during the implementation of the enforcement strategy in order for it to be evaluated properly. In addition to identifying both compliant and non-compliant products, accurate, reliable data can be used for a variety of purposes including:

A. Conducting a statistical analysis of the data to determine if the appropriate number of samples was collected. If the sample population was large enough, it would be possible to calculate the 90% upper confidence interval (UCI) for all contaminants of concern and to draw conclusions regarding any that exceed the statutory threshold.

B. Compiling all analytical data resulting from the analysis of the target product to see if there are additional contaminants of concern

C. Comparing XRF screening levels with confirmatory analytical results to check for general trends

Identification of Non-Compliant Products

Determine appropriate enforcement response. Bottom line, non-compliant products may not be sold in California. The purveyor of non-compliant products must develop a plan detailing how the products will be managed in California. Later, after review of the case, it may be determined that an enforcement action is necessary. At that time, a decision would be made to proceed with a criminal, civil or administrative enforcement action as authorized.

Non-Compliant Product Followup Inspection

A followup inspection of the location where a non-compliant product was sampled should be completed within 30 days of notification being sent to the product purveyor. The followup inspection is a necessary final check to ensure proper management of a non-compliant product.

ATTACHMENT

Target Selection Methodology and Sampling Plan

1. Select high value, multi-faceted target(s). Criteria are as follows:
    - Definitely a package or packaging component
    - Produced in relatively high volumes/numbers
    - Potential for exposure to sensitive populations
        - Pregnant women/fetus
        - Infants and/or children
        - Elderly
    - May contain chemicals of concern outside the scope of TIP
        - Other heavy metals
        - Phthalates and/or other chemicals of concern
    - Markings or codes that allow easy identification of manufacturer, distributor or importer
    - Evaluate the potential for Environmental Justice connection

2. Organize potential targets into one of the following three categories:
    - Food, beverage or cosmetic containers
    - Non-compliant packages/containers that significantly exceed Statutory Thresholds and are produced in relatively large quantities
    - Non-compliant packages/containers where minor changes in the manufacturing process would result in compliance

3. Screen potential targets based on the following criteria:
    - Ability to readily identify manufacturer/distributor/importer
    - Ease of obtaining a minimum of 4-8 samples

4. Identify one or more targets from each category in item 2 for Phase I testing

5. Recommend candidate targets to management and obtain approval to begin Phase I testing.

6. Phase I testing consists of the following activities:
    - Acquire a minimum of 4 samples using established chain-of-custody procedure
    - Conduct XRF testing for each sample
    - Conduct phthalate screening test if appropriate
    - Document results in data spreadsheet
    - Identify candidates for Phase II testing

7. Recommend candidate targets to management and obtain approval to begin Phase II testing.

8. Phase II test criteria:
    - Any sample >100 ppm per component for any one of the regulated metals (Hg, Cd, Cr6, and Pb)
    - Any sample with sum total for the regulated metals (Hg, Cd, Cr6, and Pb) >100 ppm
    - Reproducibility of XRF test data from sample to sample is <50 ppm

9. Seek management approval to submit Phase II samples to ECL for confirmatory analysis utilizing EPA Method 3050B. Upon approval, submit approved samples to ECL using e-ARF followed by TIP e-SAR.

10. Evaluate analytical data received from ECL
    - Conduct statistical analysis of data to determine if the appropriate number of samples were collected per SW-846
    - Make one of the following determinations:
        - o If the appropriate number of samples were collected AND both the calculated mean and 90% Upper Confidence Interval for any regulated metal exceeds the Statutory Threshold, the package/container may violate the TIP law and **additional sampling is not required**
        - o If the appropriate number of samples were collected AND both the calculated mean and 90% Upper Confidence Interval for the sum of all regulated metals exceeds the Statutory Threshold, the package/container may violate the TIP law and **additional sampling is not required**
        - o If the appropriate number of samples were collected BUT either the calculated mean or 90% Upper Confidence Interval for any regulated metal, or the sum of all regulated metals exceeds the Statutory Threshold, the package/container may violate the TIP law, and **additional sampling is recommended**
        - o If the appropriate number of samples were not collected, BUT both the calculated mean for any regulated metal, and the sum of all regulated metals, exceeds the Statutory Threshold, the package/container may violate the TIP law, and **additional sampling is highly recommended**
        - o If the appropriate number of samples were not collected, BUT either the calculated mean for any regulated metal, or the sum of all regulated metals, exceeds the Statutory Threshold, the package/container may violate the TIP law, and **additional sampling is recommended**
        - o If the appropriate number of samples were not collected, BUT neither the calculated mean for any regulated metal, or the sum of all regulated metals, exceeds the Statutory Threshold, the package/container may violate the TIP law, but **additional sampling is not recommended**
        - o If the appropriate number of samples were collected, AND both the calculated mean and 90% Upper Confidence Interval for any regulated metal, or the sum of all regulated metals, do not exceed the Regulatory Threshold, the package/container appears to comply with the TIP law and **additional sampling is not recommended.**

Department of Toxic Substances Control

Laboratory and Risk Assessment Strategy Template
Toxics in Consumer Products

Tapping DTSC's scientific and research knowledge base and providing for the efficient use of laboratory resources

Goal

The primary goal of a laboratory and risk assessment strategy is to assure that the resources of the Environmental Chemistry Laboratory (ECL) and Human and Ecological Risk Division (HERD) are deployed efficiently and productively to provide pertinent and accurate scientific information on toxicity, risks, legal mandates and enforcement evidence. In addition, ECL and HERD are key resources that need to be available for development of outreach and education materials, media information and consultation with the Office of Legal Counsel (OLA) and DTSC management.

Sample and Data Management

Enforcement works with Enforcement and Emergency Response Program (EERP) staff to coordinate lab lab and field resources to create and maintain efficient sample and data flow for product testing:

A. Develop forms for sample intake and processing (such as Analysis Request Forms (ARFs) and Sample Analysis Request Forms (SARs) specific to consumer products)

B. Assist program staff in defining Data Quality Objectives (DQOs): Screening, waste classification, "total metals" analysis and tests to support human health risk assessment (rather than statutory compliance). Develop decision rules: When to do destructive testing based on screening results, which acid digestion is appropriate -- 3050B, 3051 or 3052 – and when will methods used to support risk assessment be implemented?

C. Estimate laboratory capacity: Turnaround times, staff, equipment and other lab resource allocation. Recommend additional staff or other resources, if needed

D. Facilitate pre-campaign planning between enforcement staff and ECL

E. Coordinate the timely reporting of laboratory data in formats that are useful to program staff and DTSC management

Analytical Methods Development and Validation

Standard Operating Procedures (SOPs) can enable management to plan the laboratory resources needed for surveys, investigations and enforcement initiatives. SOPs also can minimize lab workflow upsets and sample analysis delays because assets can be allocated before sampling begins. The impacts of consumer products activities on ECL's capacity to support other programs, and the need for additional staff and equipment, can be estimated.

Additionally, the work on validated SOPs and analytical methods can lead to peer-reviewed articles and possible inclusion in ECL User's Manual of consumer products-related subjects as well as ensuring that DTSC has established scientifically supported methods in the event the findings are questioned or challenged. SOPs also will provide industry with consistency on testing protocols to support Certificates of Compliance. And other states may consider, and perhaps adopt, DTSC methods for toxics in products compliance testing.

A. Conduct literature review of product testing protocols: ASTM, EU, etc.

B. Develop SOPs for microwave acid digestion methods (ECL-SCL and ECL-Berkeley)

C. Develop SOPs for the preparation and analysis of plastics and other materials in consumer products for hexavalent chromium and mercury.

D. Develop database comparing XRF screening results with acid digestion/ICP analysis. To estimate the rate of false negative results, include some samples that screen below regulatory limits by XRF. Determine if XRF has element, product, or matrix specific limitations at regulatory levels of interest.

E. Review and select laboratory methods for toxicology: ECL and HERD will collaboratively research currently available methods and/or develop methods which will provide data useful for risk assessment under product-specific exposure scenarios; Examples of currently available methods include CPSC and NIOSH methods for wipe sampling, and saline or mild acid digestion. In vitro methods used to estimate the bio-accessibility of lead in soil should also be considered when selecting appropriate methods.

F. Plan validation studies, such as inter-laboratory round robin (possible collaboration with Toxics in Packaging Clearinghouse members)

G. Standard Reference Materials (SRMs): Catalog what is available; contact suppliers to promote development of product and matrix-specifc SRMs for quality control.

Laboratory Accreditation and External Quality Assurance

A level playing field field for laboratory certification would give manufacturers, suppliers, retailers and consumers assurance that laboratory results are consistent and accurate. Qualified laboratories will be identified. Private laboratories could be prepared to operate to our standards for DTSC-contracted work, if needed.

A. Toxics in products testing laboratory accreditation bodies

- Adopt National Environmental Laboratory Accreditation Program (NELAP) model? Add product testing to California ELAP authority, with inter-state reciprocity?
- Consider non-governmental accreditation: American Association for Laboratory Accreditation (A2LA), etc.? Laboratory certification standards; Adopt ISO/IEC 17025 (2005) standards?
- Require prescriptive or performance-based methods?
- What must the Certificate of Analysis contain (format, content, signatures, etc.)?
- Mandatory QA/QC: Internal (SRMs, training, calibration, etc.) and external (PE samples)?
- Other deliverables (contents and format of data package/lab report)
- Record keeping and data archiving requirements

Emerging Contaminants

News reports regularly discuss potential risks from other metals and other inorganic and organic chemicals (antimicrobials, phthalates, PBDEs, Bisphenol A, etc.) that are not currently regulated in California. ECL and HERD are resources should DTSC consider investigating the prevalence of these chemical elements and compounds, in addition to the state's four regulated metals.

Forensic Chemistry

News reports indicate that electronic waste exported from the United States may be a source of lead and other toxins in imported toys, children's jewelry and other consumer products (see www.ban.org). It may be useful to identify the source of toxics in products to ensure they are not derived from improperly managed wastes. Using forensic chemistry approaches, DTSC might be able to distinguish between intentional and accidentally introduced regulated metals and be in a stronger position to evaluate claims of exemption filed pursuant to the Toxics in Packaging Act. Additionally, gaps in the Cradle to Cradle management of consumer products would be identified, so that toxics in products would not be recycled into new products and results could point up the need for new regulatory authority to prevent toxics from entering the marketplace. Thus far, there are two major documented approaches:

- Examine other elements present in the product -- e.g. tin in solder, antimony in lead-acid batteries.
- Isotope speciation: Lead has four stable isotopes; isotope ratio can help identify source of ore, or differentiate anthropogenic vs. natural lead in the environment.

Risk Assessment Support

HERD is the primary technical resource on issues related to risk assessment and can provide guidelines for conducting risk assessments of regulated consumer products as well as scientifically defensible, product-specific, human health risk assessments, as needed. This can allow DTSC to provide scientifically supported estimates of risk from exposure to chemicals in consumer products in support of Departmental decisions based on the potential for adverse health effects (rather than statutory compliance alone). Industry also can be provided recommendations related to conducting risk assessments of regulated consumer products.

Partner with Outreach and Education

Working with Outreach and Education, ECL and HERD officials can help inform the public, elected officials and the non-scientific business community with reference material that is accessible to their knowledge levels. Such guidance material would take the mystery out of analytical procedures and results, inform the public about potential health risks and

allow them to make informed decisions. Among the issues that could be explored are:

- Strengths, limitations and applicability of XRF screening
- Succinct descriptions of the analytical methods used to evaluate products, making distinctions between survey (qualitative) and laboratory (quantitative) procedures
- Basic toxicology related to toxics in consumer products, including the potential human health effects, receptors and potential exposure pathways, acute and chronic effects depending on exposure scenarios

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